Electronic Collection of Patient-Reported Outcome Measures in Dermatology Trials

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CLARIO.

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Introduction

Patient-reported outcomes (PROs), such as diaries or questionnaires, can be collected using electronic devices during the course of a clinical trial. Data gathered via ePROs that shows a new medication improves participant's outcomes, supports regulatory submissions. Impact of a medication on PROs is important in dermatology space because skin diseases affect participants' lives in a negative way. The aim of this research was to perform a review and analyze the use of ePRO instruments in dermatology trials.

Methods

35 dermatology trials were identified in the sample of 506 studies. PRO instruments in those trials were characterized in terms of a phase of a trial, endpoint hierarchy, study population, and data collection modality (tablet vs handheld).

Results

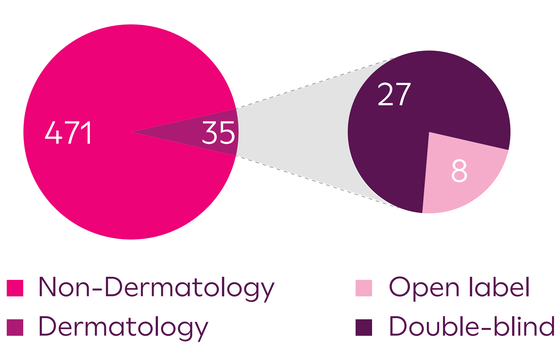

Figure 1

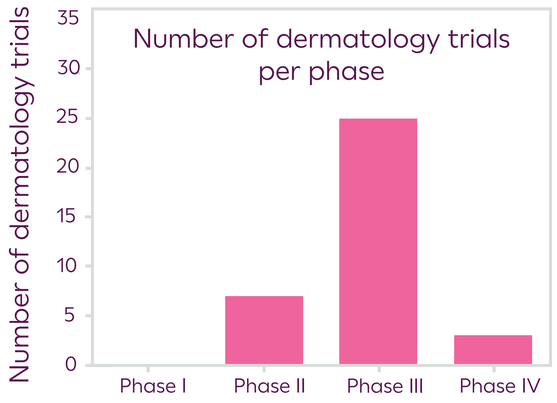

Figure 2

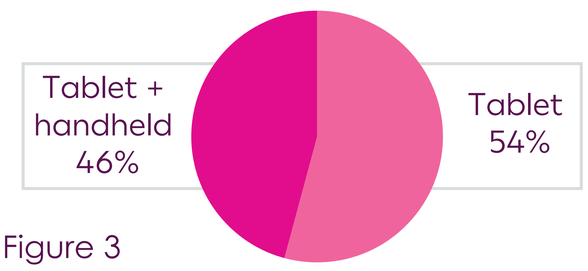

Figure 3

Table 1

Endpoint	Number of studies
Primary	3
Key Secondary	8
Secondary	15
Exploratory	9

Conclusions

Data gathered via ePROs that shows a new medication improves participant's outcomes, supports regulatory submissions.

This work shows that:

- 35 dermatology trials were identified in the sample of 506 studies. (Figure 1)
- Among 35 identified trials 100% collected ePROs.
- Among 35 trials: 7 were phase II, 25 phase III, and 3 phase IV. (Figure 2)
- 8 studies included population with age less than 18.
- ePROs supported the following outcomes: primary in 3 trials, key secondary in 8 trials, secondary in 15 trials, and exploratory in 9 trials. (Table 1)
- For the 7 trials that were completed, and ePROs supported primary and/or key secondary outcomes, 86% gained FDA approval.
- Electronic diary was used in 46% of the analyzed trials.
- Electronic diary was used in 71% of the completed trials supporting primary and/or key secondary outcomes.
- Tablet was used for data collection in 100% of the trials. (Figure 3)
- Handheld device was used for data collection in 46% of the trials. (Figure 3)
- Tablet was used for ePRO data collection during site visits and handheld was utilized for daily data collection.

Our analysis shows that around 30% of ePROs in 35 trials supported primary and/or key secondary outcomes. Generally, when dermatology trials utilized ePRO instruments, almost 50% of these studies used an electronic diary to collect data.

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